10/11/12
Statement of Dr. Madeleine Biondolillo
Director of the Bureau for Health Care Safety and Quality
Joint DPH / FDA / CDC Teleconference Call

Good afternoon, my name is Dr. Madeleine Biondolillo, Bureau Director for Health Care Safety and Quality at the Massachusetts Department of Health and Human Services. On behalf of the Commonwealth, I want to express my deepest sympathy for each person and their loved ones impacted by this tragedy. The Department of Public Health continues to closely collaborate with the CDC, the FDA, and other state public health officials to investigate the exact cause of the outbreak of *Aspergillus* (fungal) meningitis.

DPH took immediate action to protect public health and safety when first notified of the outbreak late in the evening of September 24th. NECC voluntarily surrendered its license at the request of DPH, and has recalled all medications.

Yesterday, the Board of Pharmacy issued an alert to all compounding pharmacies in the Commonwealth to reinforce for them the rules they must abide by in Massachusetts. Our statutory and regulatory requirements stipulate that compounding can only be conducted upon receipt of a patient-specific prescription. Additionally, the Board of Pharmacy has issued an order requiring that all compounding pharmacies in the Commonwealth sign an affidavit attesting compliance with all pertinent laws and regulations.

At the request of DPH -- Ameridose, LLC -- a manufacturing pharmacy in Westborough, Massachusetts that shares principal ownership with NECC, agreed to cease all manufacturing and compounding operations effective October 10. Ameridose and its partnering distributor, Alanaus Pharmaceuticals, have ceased distribution of all products manufactured and compounded by that company or any of the

companies under shared ownership for a time-delineated period.

The request for a temporary cessation of operations will facilitate a targeted, joint DPH / FDA inspection.

DPH has seen no evidence to suggest that there is direct concern for compromised product manufactured or compounded by Ameridose and has not requested a recall at this time. We are working closely with the Massachusetts Hospital Association to ensure that protection of medication supply chains. We encourage state hospital associations across the country to similarly engage with their providers.

Our shared investigation with our federal partners at the FDA continues and will be comprehensive. This includes concerns for quality and safety across the corporate entity, including, but not limited to, corporate ownership and governance structures at NECC and Ameridose. We urge Congress to act quickly to address the need for new laws on the federal level to fill in the regulatory gaps, so that there is clear authority over regulating these practices.

DPH and FDA are jointly examining all root causes of these events, and we are committed to ensuring that all responsible parties are held accountable.